

REMARKS

This Amendment is responsive to the Office Action dated December 2, 2008. Applicant has amended claims 17, 18–19, 36, 39, 43–44, and 46, cancelled claim 41 without prejudice, and added new claims 47–49. Applicant previously cancelled claims 1–16, 20–35, and 38. Thus, claims 17, 18–19, 36, 37, 39–40, and 42–49 are pending upon entry of this Amendment.

Interview Summary Record

As per the requirements of MPEP §713.04, the present summary constitutes a summary record of the substance of the interview between Applicant's representative, Raymond R. Berdie (Reg. No. 50,769), and the Examiner (Phillip A. Gray) on February 23, 2009. Applicant's representative wishes to thank the Examiner for agreeing to this telephonic interview.

During the interview, Applicant's representative and the Examiner discussed the following items with respect to the Office Action mailed on December 2, 2008: (1) the rejection of claims 17–19, 36–37, and 39–46 under 35 U.S.C. 102(b) as anticipated by Sandmore et al. (US 6,059,760); and (2) the rejection of claims 17–19, 36–37, and 39–46 under 35 U.S.C. 103(a) as obvious in view of Sandmore et al. (US 6,059,760) and Jones et al. (US 5,843,050). Applicant's representative also discussed certain proposed amendments to the claims with the Examiner regarding a flow of fluid through and out of the elastic restrictor. Applicant's representative argued that the applied references fail to disclose or suggest each and every feature of the claims. No formal agreement was reached.

Claim Rejections Under 35 U.S.C. §§ 102, 103

In the Office Action, the Examiner rejected claims 17–19, 36–37, and 39–46 under 35 U.S.C. 102(b) as anticipated by Sandmore et al. (US 6,059,760, hereinafter "Sandmore"). In the alternative, the Examiner rejected claims 17–19, 36–37, and 39–46 under 35 U.S.C. 103(a) as obvious in view of Sandmore and Jones et al. (US 5,843,050, hereinafter "Jones"). Applicant respectfully traverses these rejections to the extent they may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

Applicant has amended each of independent claims 17 and 36. Each of these independent claims requires, on a sidewall of a catheter or catheter assembly, a plurality of openings, at least one of which is angled towards a proximal end of a tubular structure or catheter assembly. These claims also require an elastic restrictor that, when operable, changes in size in response to a change in fluid flow to provide a variable amount of fluid force restriction as fluid flows through the elastic restrictor, such that forces resulting from fluid flow out of the openings and from fluid flow out of the elastic restrictor are substantially balanced in both axial and radial directions. As amended, these claims require that, when the catheter or catheter assembly is operable, fluid flows through and out of the elastic restrictor. Sandmore fails to disclose or suggest each of these claim elements.

Applicant first notes that fluid outlets 100 disclosed in Sandmore (and as shown in FIGS. 13–14, for example) are located on a sidewall 102 of the cannula tip 45'. Applicant further notes that the only opening on an end 104 of cannula tip 45' in Sandmore is tiny aperture 132, shown in FIGS. 13–14. However, Sandmore states that the end 104 is **a substantially closed distal end 104 that prevents fluid from exiting therethrough.**¹ Tiny aperture 132 is only provided to prevent air from becoming entrapped in the distal end of cannula tip 45'.²

Sandmore fails to disclose or suggest a catheter or catheter assembly having an elastic restrictor through which fluid may flow and also, on a sidewall, one or more openings arranged such that forces resulting from fluid flow out of the openings and from fluid flow out of the elastic restrictor are substantially balanced in both axial and radial directions, as required by amended claims 17 and 36. Columns 8–9 of Sandmore make it clear that substantially closed end 104 of the cannula tip 45', which includes tiny aperture 132, **prevents fluid from exiting therethrough.** Tiny aperture 132 is included only to prevent air from becoming entrapped in the distal end of cannula tip 45'. Therefore, only fluid outlets 100 of Sandmore are capable of allowing fluid to exit therethrough. Fluid outlets 100 extend toward the proximal end 116 and reverse the flow of fluid exiting from the cannula tip 45'.³

Therefore, because fluid exits only out of fluid outlets 100 in Sandmore, and is not capable of exiting out of tiny aperture 132, Applicant submits that Sandmore fails to disclose or suggest an elastic restrictor through which fluid may flow. Applicant further submits that, in

¹ Col. 8, lines 33–37 of Sandmore.

² Id. See also FIG. 14 of Sandmore.

³ Col. 8, lines 11–13 of Sandmore.

Sandmore, forces resulting from fluid flow out of fluid outlets 100 and tiny aperture 132 **cannot** be substantially balanced **in both axial and radial directions**, because no fluid exits through tiny aperture 132. Because no fluid exits through tiny aperture 132, there does not exist any forward force component (in an axial direction) to counterbalance the rearward force components resulting from the reversed, angled fluid flow out of fluid outlets 100. Thus, forces resulting from fluid flow in Sandmore cannot possibly be substantially balanced in an axial direction, let alone in both axial and radial directions.

In those embodiments of Sandmore in which a multi-lumen cannula is disclosed, Applicant does not believe that forces resulting from fluid flow out of fluid outlets 100 can be balanced in **either** of the axial or radial directions. Additionally, even if one were to try and interpret aperture(s) 28' of Sandmore as an elastic restrictor (which Applicant does not believe is a proper interpretation of elastic restrictor within the meaning of the claims), forces resulting from fluid flow out of fluid outlets 100 and from fluid flow out of aperture(s) 28' cannot be substantially balanced in both axial and radial directions. For at least these reasons, Sandmore fails to disclose or suggest each and every element of amended claims 17 and 36.

Applicant further submits that Jones fails to overcome the shortcomings of Sandmore. In the Office Action, the Examiner referred to Figures 5 and 7, along with lines 14–63 of column 11, of Jones. These portions of Jones disclose an aperture 88 on a distal segment 72. Aperture 88 accommodates a guidewire to pass therethrough.⁴ While aperture 88 may permit the escape of pressurized media, such as contrast media or medication, only a relatively small volume of fluid may flow through aperture 88 in order to prevent stagnation in the vessel at the distal end of the catheter.⁵ Most of the fluid exiting distal segment 72 flows out of a plurality of lateral apertures 74.⁶ Applicant submits that forces resulting from fluid flow out of these lateral apertures 74 and out of aperture 88 cannot be substantially balanced in both axial and radial directions.

Firstly, the majority of the fluid flows out of apertures 74, while only a minimal amount may exit aperture 88. In addition, it appears from the disclosure of Jones that fluid exits out of lateral apertures 74 in directions substantially **perpendicular** to the direction of flow of the small volume of fluid that may flow out of aperture 88. In this case, it would not be possible for the

⁴ Col. 11, lines 45-51 of Jones.

⁵ See col. 10, lines 60-64 and col. 11, lines 21-22 of Jones.

⁶ See, e.g., FIG. 5 of Jones.

forces resulting from fluid flow out of the lateral apertures 74 and aperture 88 to be substantially balanced in both axial and radial directions, because there are no rearward force components (in an axial direction) to counterbalance any forward force component that results from fluid out of aperture 88. Thus, forces resulting from fluid flow in Jones cannot possibly be substantially balanced in an axial direction, let alone in both axial and radial directions. For at least these reasons, Jones also fails to disclose or suggest each and every element of amended claims 17 and 36.

Claims 18–19, 37, and 39–40, and 42–46 depend, either directly or indirectly, on either claim 17 or 36. For at least the reasons outlined above, Applicant submits that neither Sandmore nor Jones, alone or in combination, discloses or suggests each and every element of these dependent claims.

Therefore, for at least these reasons, Applicant respectfully submits that the applied references fail to establish a prima facie case for the un-patentability of Applicant's claims 17–19, 36–37, and 39–40, and 42–46 under either 35 U.S.C. 102(b) or 35 U.S.C. 103(a). Withdrawal of the rejections to these claims is therefore respectfully requested.

New Claims

Applicant has added claims 47–49 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the applied references fail to disclose or suggest any form of elastic restrictor, within the meaning of Applicant's claims, which is not formed or included on a sidewall of a catheter/assembly. No new matter has been introduced by claims 47–49.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

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